510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k050321

B. Purpose for Submission:
The purpose is to obtain a new 510(k) number(s) under new ownership, Varian, Inc.

C. Measurands:
Amphetamine Barbiturate, Benzodiazepine Cocaine, Methamphetamine, Morphine, PCP, Tricyclic Antidepressant, and THC.

D. Type of Test:
Competitive microparticle capture inhibition.

E. Applicant:
Varian, Inc.

F. Proprietary and Established Names:
Varian, Inc. OnTrak TesTCARD™ 9

G. Regulatory Information:

1. Regulation section:
   (See below table)
2. Classification:
   All Class II
3. Product Code:
   (See below table)
4. Panel:
   Toxicology (91)

Analytes	Classification Name	CFR Classification Number	Product Code
Amphetamine	Amphetamine Test System	21 CFR 862.3100	91DKZ
Barbiturates	Barbiturate Test System	21 CFR 862.3150	91DIS
Benzodiazepines	Benzodiazepine Test System	21 CFR 862.3170	91JXM
Cocaine	Cocaine Test System	21 CFR 862.3250	91DIO
Methamphetamine	Methamphetamine Test System	21 CFR 862.3610	91LAF
Morphine	Morphine Test System	862.3640	91DJJ
PCP	PCP Test System	Not Assigned	91LCM
Tricyclic Antidepressant	Tricyclic Antidepressant Test System	21 CFR 862.3910	91LFG
THC	Cannabinoid Test System	21 CFR 862.3870	91LDJ

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below

2. Indication(s) for use:

   The OnTrak TesTCARD® 9 is an in vitro diagnostic test intended for use by health care professional only for the qualitative detection of drug or drug metabolites in urine. The On Trak TesTCARD 9 simultaneously tests for the presence of multiple drugs or drug metabolites at or above the stated concentrations.

   Cutoff Concentrations:

Amphetamines – 1000 ng/mL	Morphine – 300 ng/mL
Barbiturates – 200 ng/mL	PCP (phencyclidine – 25 ng/mL
Benzodiazepines – 100 ng/mL	Tricyclic Antidepressants -1000 ng/mL
Cocaine metabolite – 300 ng/mL	Tetrahydrocannabinol (TCH) 50 ng/mL
Methamphetamine – 500 ng/mL	

   On Trac TesTCARD 9 product provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography mass spectrometry (GC/MS) is the preferred confirmation method. Clinical consideration and professional judgement should apply to any drug of abuse test result, particularly when positive results are used.

3. Special condition for use statement(s):

   The On Trac TesTcard 9 product provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/Mass spectrometry is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

4. Special instrument Requirements:
   Not applicable. The device is a visually read single-use device.

I. Device Description:

The device is a cassette containing nine strips. Each strip contains a test region and a Test Validation region, which serves as a process control. The test is based on microparticle capture inhibition. Drug which may be present in the urine competes with drug conjugate immobilized on the strip's membrane for binding

to antibody coated blue microparticles. In the absence of drug in the urine the antibody-coated blue microparticles bind to the immobilized drug conjugate and form a band in the test region. The test is visually read.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Roche Diagnostics Corporation, On Trak TesTcard 9

2. Predicate K number(s):

   k012396

3. Comparison with predicate:

   This device is unchanged. It has the same intended use, indications for use and is based upon the same technology.

K. Standard/Guidance Document Referenced (if applicable):

The standards were referenced in k012396.

L. Test Principle:

The TesTcard 9 assay is based on the principle of microparticle capture inhibition.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   The precision was previously established in k012396

   b. Linearity/assay reportable range:

   Not applicable. The assay is intended for qualitative use.

   c. Traceability (controls, calibrators, or method):

   Traceability for this device was determined in k012396.
   The device has an internal process control. Users are instructed to follow federal, state, and local guidelines when determining when to run external controls.

   d. Detection limit:

   Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration of the assay, including a determination of the lowest concentration of drug that is capable of

producing a positive result. Detection Limits for this device were determined in k012396.

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine /a negative control. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. The Analytical Specificity for this device was determined in k012396.

f. Assay cut-off:

The TesTcard 9 cutoff levels were based on US federal mandatory guidelines for SAMHSA (Substance Abuse and Mental Health Services Administration) drugs with the exception of morphine which has a SAMHSA cutoff level of 2000 ng/mL and benzodiazepines, barbiturates, methamphetamine and TCA which have no SAMHSA cutoff levels.[1]

Cutoff Concentrations:

Amphetamines – 1000 ng/mL
Barbiturates – 200 ng/mL
Benzodiazepines – 100 ng/mL
Cocaine metabolite – 300 ng/mL
Methamphetamine – 500 ng/mL
Morphine – 300 ng/mL
PCP (phencyclidine – 25 ng/mL
Tetrahydrocannabinol (TCH) 50 ng/mL
Tricyclic Antidepressants -1000 ng/mL

1. Mandatory Guidelines for Federal Workplace Drug Testing Programs. Federal Register September 30, 1997. Department of Health and Human Services Administration.

2. Comparison studies:

a. Method comparison with predicate device:

The method comparisons were determined in k012396.

b. Matrix comparison:
Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:
    a. *Clinical sensitivity:*
    Not applicable. Clinical studies are not typically submitted for this device type.

    b. *Clinical specificity:*
    Not applicable. Clinical studies are not typically submitted for this device type.

    c. *Other clinical supportive data (when a and b are not applicable):*

4. Clinical cut-off:
    Not applicable.

5. Expected values/Reference range:
    Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.